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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,909	11/24/2003	Roland Janzen	DCS-9151	5291
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DADE BEHRING INC. LEGAL DEPARTMENT 1717 DEERFIELD ROAD DEERFIELD, IL 60015			EXAMINER VENC1, DAVID J	
			ART UNIT 1641	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/720,909

**Applicant(s)**

JANZEN ET AL.

**Examiner**

David J. Venci

**Art Unit**

1641

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on April 24, 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 9-12 and 14-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 9-12 and 14-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☒ Claim(s) 1-7, 9-12 and 14-21 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Examiner acknowledges Applicants' reply filed April 24, 2008. Claim 8 is cancelled.

Claims 1-7, 9-12 and 14-21 are pending in this application. Claims 1-6, 9-12 and 14-21 are directed to non-elected inventions and were withdrawn from consideration pursuant to 37 C.F.R. 1.142(b) in the Office Action dated January 25, 2008.

Claim 7 is under examination.

This application was filed under 35 U.S.C. § 111(a) on November 24, 2003. No claims of priority to an earlier filing date have been made.

### ***Claim Objections***

Claim 7 is objected to because there appears to be too many semicolons. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

#### ***New Matter Rejection***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

As amended, claim 7 appears to require:

A. a reagent comprising:

1. fluid medium;
2. substrate-attached biotin; and
3. a porous material having a scavenger-coated inner surface.

B. a reagent comprising:

1. fluid medium;
2. substrate-attached avidin; and
3. a porous material having a scavenger-coated inner surface.

C. a reagent comprising:

1. fluid medium;
2. substrate-attached antigen; and
3. a porous material having a scavenger-coated inner surface.

D. a reagent comprising:

1. fluid medium;
2. substrate-attached antibody; and

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3. a porous material having a scavenger-coated inner surface.

E. a reagent comprising:

1. fluid medium;
2. substrate-attached hapten; and
3. a porous material having a scavenger-coated inner surface.

F. a reagent comprising:

1. fluid medium;
2. substrate-attached receptor; and
3. a porous material having a scavenger-coated inner surface.

G. a reagent comprising:

1. fluid medium;
2. substrate-attached oligonucleotide; and
3. a porous material having a scavenger-coated inner surface.

Examiner is unable to locate support in the specification for each of newly claimed reagents A through G, *supra*. Applicants are required to cancel new matter in response to this Office Action.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Bittner & Rowold, *Electrotransfer in Equipment Containing Buffer*, in CRC HANDBOOK OF IMMUNOBLOTTING OF PROTEINS, Vol. 1, Chapter 4.3.1, pp. 69-77, O.J. Bjerrum & N.H.H. Heegaard, Eds., CRC Press, Inc. (1988).

Bittner & Rowold describe a reagent intended to capture free binding species in a fluid medium containing both free binding species and binding species attached to a substrate, wherein the binding species attached to the substrate is intended to disassociate from the substrate, the reagent comprising:

a fluid medium (see p. 72, Step 2—Electroblotting, "The buffer tank should contain sufficient precooled buffer to cover the filter sandwich"; see *a/so*, Fig. 1A, "Buffer Tank") containing:

1. a substrate having binding species attached to the substrate (see p. 69, second paragraph, first sentence, "proteins to be eluted from gels"; see *a/so*, Fig. 1B, "Gel"), wherein the binding species is an antigen receptor (see p. 69, first paragraph, second sentence, "antigen"); and
2. a porous material (see Fig. 1B, "Immobilizing Filter") having:
  - a. permeability to free binding species (see Fig. 1B, "Immobilizing Filter") (emphasis added); and
  - b. a scavenger coating for free binding species within the pores of the porous material (see p. 74, third full paragraph, second sentence, "immobilization throughout the coarser covalent matrices"; see *a/so*, Fig. 1B, *noting* a thick "Immobilizing Filter"; see *a/so*, p. 71, line 1, "cyanogen bromide activated paper");

wherein the porous material is not intended to have permeability to said substrate (see Fig. 1B, *noting* that Fig. 1 fails to particularly point out and distinctly claim a "Gel" permeating into the "Immobilizing Filter").

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Skold *et al.* (US 5,039,607).

Skold *et al.* describe a reagent intended to capture free binding species in a fluid medium containing both free binding species and binding species attached to a substrate, wherein the binding species attached to the substrate is intended to disassociate from the substrate, the reagent comprising:

a fluid medium (see col. 20, line 5, "the first and second bibulous strips can be immersed in a developer solution") containing:

1. a substrate having binding species attached to the substrate (see col. 19, lines 59-61, "the second reagent all becomes bound to the first bibulous member"), wherein the binding species is selected from the group consisting of biotin (see col. 14, lines 55-56, "biotin"), avidin (see col. 7, line 57, "avidin"), antigen (see col. 8, line 40, "analyte surrogate"), antibody (see col. 7, line 50, "immunoglobulins"), receptor (see col. 7, lines 48, "receptor analytes"), and oligonucleotides (see col. 7, line 57, "DNA, RNA"); and
2. a porous material (see col. 19, lines 61-62, "the second bibulous strip") having:
  - a. permeability to free binding species (see col. 19, lines 61-62, "the second bibulous strip") (emphasis added); and

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- b. a scavenger coating for free binding species within the pores of the porous material (see col. 19, lines 54, "captured by the antibody on the second bibulous strip"; see *also*, col. 9, lines 1-6, "Binding of receptors and antibodies to the bibulous material may be accomplished by[...] the literature") (paraphrasing);

wherein the porous material is not intended to have permeability to said substrate (see entire document, *noting* that Skold *et al.* fail to particularly point out and distinctly claim a "first bibulous member" permeating into the "second bibulous member").

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dittmer *et al.*, 10 ELECTROPHORESIS 762 (1989), in view of Elkon, K.B., *Capillary Blotting and Contact Diffusion*, in CRC HANDBOOK OF IMMUNOBLOTTING OF PROTEINS, Vol. 1, Chapter 4.1, pp. 51-59, O.J. Bjerrum & N.H.H. Heegaard, Eds., CRC Press, Inc. (1988).

Dittmer *et al.* describe a reagent intended to capture free binding species in a fluid medium containing both free binding species and binding species attached to a substrate, wherein the binding species attached to the substrate is intended to disassociate from the substrate, the reagent comprising:



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1. a substrate having binding species attached to the substrate (see p. 763, left column, section 2.4 *Isoelectric focusing*, last sentence, "The samples[...] were applied onto the gel"), wherein the binding species is streptavidin (see Abstract, first sentence, "streptavidin[...] analyzed by isoelectric focusing"); and
2. a porous material (see p. 763, left column, section 2.6 *Affinity protein blotting*, first sentence, "biotinylated NC filter") having:
  - c. permeability to free binding species (see p. 763, left column, section 2.6 *Affinity protein blotting*, first sentence, "biotinylated NC filter") (emphasis added); and
  - d. a scavenger coating for free binding species within the pores of the porous material (see p. 763, left column, section 2.6 *Affinity protein blotting*, first sentence, "biotinylated NC filter"; see *also*, Abstract, first sentence, "biotinylated, protein saturated nitrocellulose") (emphasis added);

wherein the porous material is not intended to have permeability to said substrate (see entire document, *noting* that Dittmer *et al.* fail to particularly point out and distinctly claim a "gel" permeating into the "NC filter").

Dittmer *et al.* do not describe a "fluid medium containing;".

However, Elkon describes such a "fluid medium" containing, for blotting procedures similar to Dittmer's blotting procedure (see Title, "Capillary blotting and contact diffusion"), for example, glass baking dish- and plexiglass tank- fluid media containing, for example, paper filter- or towel containing, reagents (see paragraph bridging pp. 51-52 and Fig. 1).

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It would have been obvious for persons of ordinary skill to provide Dittmer's blotting reagents with a "fluid medium containing," because Elkon says such reagents are "required" (see paragraph bridging pp. 51-52 and Fig. 1), probably because such reagents enable capillary flow of buffer (see p. 51, second paragraph, second sentence) prior to toweling off (see p. 51, last full paragraph, first sentence).

### ***Response to Arguments***

In prior Office Action, claim 7 was rejected under 35 U.S.C. 102(b) as being anticipated by Bittner & Rowold, *Electrotransfer in Equipment Containing Buffer*, in CRC HANDBOOK OF IMMUNOBLOTTING OF PROTEINS, Vol. 1, Chapter 4.3.1, pp. 69-77, O.J. Bjerrum & N.H.H. Heegaard, Eds., CRC Press, Inc. (1988). And, claim 7 was rejected under 35 U.S.C. 102(b) as being anticipated by Skold *et al.* (US 5,039,607).

In response, Applicants amend claim 7 to require specific "binding species" and a porous material having a "scavenger-coated" inner surface. Applicants argue that the cited prior art does not teach claim 7 requiring both a specific "binding species" and a porous material having a "scavenger-coated" inner surface.

Applicants' arguments have been carefully considered but are not persuasive.

Bittner & Rowold describe "antigen" or "receptor" binding species (see p. 69, first paragraph, second sentence, "antigen"), which may be captured in a porous material having a scavenger-coated inner surface (see p. 71, line 1, "cyanogen bromide activated paper").

Skold *et al.* describe several analyte binding species, including biotin (see col. 14, lines 55-56, "biotin"), avidin (see col. 7, line 57, "avidin"), antigen (see col. 8, line 40, "analyte surrogate"), antibody (see col. 7,

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line 50, "immunoglobulins"), receptor (see col. 7, lines 48, "receptor analytes"), and oligonucleotides (see col. 7, line 57, "DNA, RNA"), which may be captured in a porous material having a scavenger-coated inner surface (see col. 9, lines 1-6, "Binding of receptors and antibodies to the bibulous material may be accomplished by[...] the literature") (paraphrasing).

### ***Conclusion***

Claim 7 is not allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is (571)272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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